

APR - 1 2005

Premarket Notification 510(k)
bioMérieux, Inc.
MDA® B.30

K050513

510(k) SUMMARY

(a)(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared:

Submitter's Name: bioMérieux, Inc.

Submitter's Address: 100 Rodolphe Street
Durham, North Carolina 27712

Submitter's Telephone: (919) 620-2968

Submitter's Contact: Jocelyn Jennings, RAC
Associate Staff RA Specialist

Date 510(k) Summary prepared: February 22, 2005

(a)(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Trade or Proprietary Name: MDA® 180:MDA II (B.30 software)

Common or Usual Name: Coagulation instrument

Classification Name: 21CFR864.5425
Multipurpose system for in vitro
coagulation studies

(a)(3) An identification of the legally marketed device to which the submitter claims substantial equivalence:

Device Equivalent to: MDA® 180:MDA® B.23

(a)(4) A description of the device

Device Description:

The Multi-Channel Discrete Analyzer (MDA) system is a fully automated, random access analyzer used to perform clinical analyses related to hemostasis and thrombosis. The instrument determines results or reaction rates by detecting changes in the light transmitted through a reaction mixture. Flexibility in optics, fluidics, and software allow the MDA to perform many different assays including traditional clotting assays, chromogenic assays, and immunoassays.

The MDA B.30 software version Q08.00 is an update to the MDA B.23 software version Q05.00 and was developed with the same intended use.

The modifications to the MDA B.30 software consists of the following:

1. add new methods in order to accommodate new OEM supplied chromogenic reagents;
2. new endpoint algorithms to reduce the erroneous error rate without increasing the erroneous result rate;
3. new wash macro for Simplastin HTF to minimize precipitate build up in Probe D;
4. add a new B4 latex method to allow customers to validate a Free Protein S assay;
5. add Italian and Spanish languages; and
6. new and enhanced waveform analysis features

(a)(5) A statement of the intended use of the device.

Device Intended Use:

The MDA is a multipurpose system for in vitro coagulation studies and is capable of running various clot based, chromogenic and immunoassays.

(a)(6) A summary of the technological characteristics of the new device in comparison to those of the predicate device.

The data contained in this submission support the claim that the MDA B.30 software is substantially equivalent to the MDA B.23 software in terms of intended use, functional requirements and performance. The MDA instrument platform that contains B.23 software is the exact same instrument platform that contains B.30 software. The operating system, optics, sample type, reagent assays and target population are identical for both versions of software.

(b)(1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the Premarket notification submission for a determination of substantial equivalency.

There were no nonclinical tests, referenced or relied on for this submission.

- (b)(2) **The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3).**

Precision data for the 12 representative assays were all well within the criteria stated. There was 100% agreement between the predicate software B.23 and new software version B.30 for all methods. MDA b.30 demonstrated its ability to determine correct clotting times for samples that had increased levels of interfering substances.

The erroneous result rate was much improved in B.30 when compared to B.23.
The erroneous error rate was much improved in B.30 when compared to B.23.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Jocelyn Jennings, RAC
Associate Staff Regulatory
Affairs Specialist
bioMerieux, Inc.
100 Rodolphe Street
Durham, North Carolina 27712

APR - 1 2005

Re: k050513
Trade/Device Name: MDA® 180:MDA II (B.30 software)
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: II
Product Code: JPA
Dated: February 25, 2005
Received: March 1, 2005

Dear Ms. Jennings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

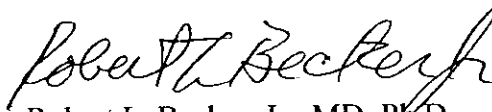
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 –

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in black ink, reading "Robert L. Becker, Jr." with a stylized flourish at the end.

Robert L. Becker, Jr., MD, Ph.D

Director

Division of Immunology and Hematology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

INDICATIONS OF USE FORM

510(k) Number (if known): K050513

Device Name: MDA®:MDA® II (B.30 software)

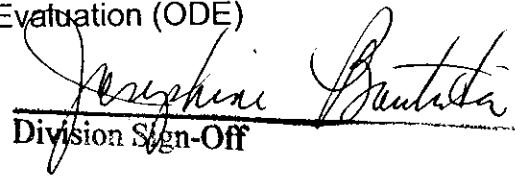
Indications For Use:

The MDA is a multipurpose system for in vitro coagulation studies and is capable of running various clot based, chromogenic and immunoassays.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)


Division Sign-Off

Office of In Vitro **Diag**
Evaluation and **Safety**

510(k) K050513